

Notice of Allowability

Application No.

09/734,221

Examiner

Bao Qun Li

Applicant(s)

LITTMAN ET AL.

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed on 06/21/2006.
2. ☒ The allowed claim(s) is/are 37.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>08/18/2006</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Bao Qun Li

EXAMINER'S AMENDMENT

The amendment filed on June 16, 2006 has been acknowledged. Claims 37 and 74 have been amended. New claims 75-80 have been added. Claims 27-32 and 41-60 were canceled. Claims 1-26, 33-40, 61-80 are pending. Claims 1-26, 33-36, 38-40, 61-72 have been withdrawn from consideration. Claims 37, 73 and 74-80 are considered by the examiner.

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney, Veronic Mallon on August 18, 2006.

The application has been amended as follows:

Claim 37 (current amended)

In line 3 please insert --- said --- before "entry"

In line 4 please delete "CCR5" and substitute it with --- CC-CKR5 ---

In line 5 please insert --- target --- after "said"

In lines 6-7 please delete "a macrophage-tropic HIV virus or"

In lines 12-13 please delete "the macrophage-tropic HIV virus or"

In line 14-16, please delete "wherein fusion is measured by a method selected from the group consisting of visual (microscopic) assessment or syncytia formation, measurement of reporter gene expression and measurement (FACS)" and inserted after "target cell," --- wherein the measurement of said fusion is performed by a fluorescence intensity detection or by a fluorescence activated cell sorting (FACS) analysis ---

In line 18 please delete " the macrophage-tropic HIV virus or" and insert --- said --- before "fusion"

Please cancel claims 1-26, 33-36, 38-40, 61-80.

Claim 37 is allowed and re-written as follow:

37. A method of identifying an agent that inhibits entry of a macrophage-tropic HIV virus into a target cell, wherein said entry of the macrophage-tropic HIV into said target cell is a

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fusion process mediated by CC-CKR5 and CD4 expressed on the surface of said target cell, the method comprising the steps of :

- (a) contacting said target cell with a virus pseudotyped with a macrophage-tropic HIV envelope in the presence or absence of said agent;
- (b) measuring the fusion between the virus pseudotyped with a macrophage-tropic HIV envelope and said target cell, wherein the measurement of said fusion is performed by a fluorescence intensity detection or by a fluorescence activated cell sorting (FACS) analysis, and
- (c) determining whether said fusion of the virus pseudotyped with a macrophage-tropic HIV envelope is inhibited in the presence of the agent but not in the absence of the agent.

2. The following is an examiner's statement of reasons for allowance: The claimed invention is directed to a unique screening assay for identifying an agent that inhibits the macrophage-tropic HIV virus (M-tropic) infection at the time when the application was originally filed, wherein the inhibition is specifically targeted at the initial step of M-trop virus entry of a M-tropic HIV envelope binding and fusing processes mediated by β chemokine receptor CC-CKR5 expressed on the CD4+ target cell surface. The novelty of the claimed invention is to see the inhibitor targeted at the fusion process between a fluorescent reporter virus pseudotyped with a macrophage tropic HIV-1 (M-tropic) envelope via a CCKR5 on CD4 + target cells rather than any other steps by using a M-tropic HIV-1 virus to infect said target cell. Because said reporter virus pseudotyped M-tropic HIV envelope protein only has one life cycle, and it cannot replicate to infect other cell. Whether the fusion between said pseudotyped virus and the target cell is solely depended on if the target cell expressing CC CKR5 and the binding envelope is M-tropic HIV envelope. The applicants are the first group at the time the application was originally filed, who disclosed to use a reporter virus pseudotyped with a HIV M-tropic envelope protein to infect CC-CKR5 expressing CD4+ target cell and using said system to determine that the inhibition of HIV-1 M-tropic virus infection by β chemokine is to block the fusion process rather than any other process or possible mechanisms. Cocchi et al. did not teach,

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disclose or even suggest such mechanism that why β chemokine could suppress the M-tropic HIV infection in PM1 cells (See pages 1813-1814).

3. No prior art prior to the provisional application SN 60/017,157 of current application was filed on May 20, 1996, teaches or suggests to use a reporter virus pseudotyped with M-Tropic HIV-1 envelope to establish a fusion assay with a target cell exclusively required to express CC-CKR5 and CD4 on the cell surface and use said fusion assay to identify a therapeutic agent target at the fusion step of a M-tropic HIV infection.

4. The support for the claimed invention and amendment can be found in the current application and provision application SN 60/017,157. Especially, in the last paragraph of page 5, examples 1-3, the descriptions of Figures 1-3 and claim 35 of the provisional application SN 60/017,157 as well as the claims in the current application. Therefore, claim 37 benefits the earlier priority date of the provisional application SN 60/017,157, filed on May 20, 1996.

5. While another group lead by Allaway et al. describes a similar assay in their patent No. 6,344,545B1 (See column 12) and other related applications. However, said assay was only disclosed until June 14, 1996 in the provisional application SN. 60,019,715, but it was not taught or suggested in the provisional application SN. 60,014,532, filed on April 02, 1996. Therefore, patent No. 6,344,545B1 or its related family of patents or applications cannot be used as 102(e) reference to reject claim 37 of the current application. There is no interference found in the issued patents and published applications.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bao Qun Li

BAOQUN LI, MD
PATENT EXAMINER